

The FDA and Terfenadine

TO THE EDITOR: In the article by Zechnich and co-workers on interactions between the antihistamines terfenadine and astemizole and other agents, the authors conclude that "informing physicians may have limited efficacy in preventing episodes of concurrent use" of terfenadine or astemizole and macrolides or antifungal azoles.^{1(p324)} We agree with them that educational efforts do not necessarily result in improved performance by the targeted population. For example, intensive measures such as special programs, the use of videotapes, and in-service sessions have failed to increase the compliance of health care workers with infection control practices.^{2,4} This behavior is inexplicable; unlike potential drug reactions, these practices consistently decrease the incidence of hospital-acquired infections.

This phenomenon, however, is not limited to physicians or nurses. In their study, Zechnich and colleagues showed that the same pharmacy was involved in 97% of concurrent-use episodes. Pharmacists continued to dispense medications with potentially hazardous side effects despite interventions by pharmaceutical companies—at least after the earlier warning letters—targeting not only physicians but also pharmacists.

We agree with the authors that their study period does not permit the measurement of the full effect of governmental and industrial warning campaigns. But because the best outcome is usually seen soon after an intervention, we examined the effect that the July 1992 US Food and Drug Administration (FDA) public warning may have had on terfenadine use. We extrapolated the maximum number of terfenadine tablets prescribed during June, August, and September of 1991 and 1992 from Figure 1 in their report.^{1(p322)} By comparing terfenadine use during and after the allergy season in both years, we found that the FDA's press release had a significant effect on the number of prescriptions (χ^2 , $P < .0001$). Although there was a trend toward significance for the relationship between the FDA release and estimates of concurrent-use episodes during the months of June and September of both years (Figure 2),^{1(p323)} no conclusions could be drawn. The number of episodes is small and is a function of prescribed terfenadine.

We conclude that the FDA's public warning had an effect on dispensing terfenadine and possibly on the concurrent prescribing of other drugs. Although we do not know who was ultimately responsible for the reduction in terfenadine use—physicians or pharmacists—we suspect it was both.

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Drs Zechnich and Haxby Respond

TO THE EDITOR: The comments submitted by Dr Hakim and Ms Stahl are appreciated. In particular, they provide references to other published reports that document the limited effect of some educational programs in changing the practice behavior of health care professionals. There may be many reasons for this limited effect. In the case of prescribing possibly interacting medications, we hypothesize that prescribers may have limited information regarding a patient's full medication profile. In 48% of the episodes of concurrent prescribing in our report, patients received the two medications from different physicians. Even if these prescribers were aware of the possible interaction, access to the full medication profile may be limited in many cases, and thus, educational efforts for physicians alone also may be limited. Informing pharmacists is a key component of any such educational efforts.

We have serious concerns regarding these authors' analysis of the data published in the original report. According to their analysis, the number of terfenadine prescriptions before and after the allergy season varied between 1991 and 1992 to a degree unlikely to be caused by chance alone. The conclusion that this difference must be because of the US Food and Drug Administration (FDA) press release without controlling for significant confounding effects is unfounded, however. As discussed in the original report, because of the natural lag between dispensing medication and submitting a claim to Medicaid, we cannot assume that data are complete from August and September 1992. Natural variation from year to year or within a given allergy season may be substantial and may affect the volume of antihistamines prescribed. We suspect that many prescribers may have switched patients to astemizole therapy, further reducing terfenadine prescribing without reducing potential risk. Finally, prescribers may have become aware of these interactions from sources other than the FDA press release. When the Drug Use Review of Oregon notified the physicians and pharmacists who were identified in our investigation about the concurrent prescribing, we surveyed these health care workers. Of responding physicians, 42% reported that they learned about this interaction from the manufacturer's letter and 12% as a result of the press release. In short, the presence of these confounding variables limits the ability to draw reliable conclusions. Furthermore, such analysis must focus on the extent of concurrent prescribing, rather than the number of terfenadine prescriptions. In fact, their analysis of concurrent prescribing failed to show a statistical difference.

While we believe that efforts such as the FDA press release are essential and probably do have considerable effect, the limited data in our investigation cannot support this conclusion. Perhaps a well-controlled time-series analysis would more accurately assess this issue, and we are currently pursuing such an evaluation. While researchers continue to try to identify the best way to prevent interactions, such widespread efforts to inform health care professionals should be strongly encouraged.

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Oregon Health Plan—Clarification

TO THE EDITOR: I found the Special Series in the July issue on health care reform to be interesting and informative. As one of the original Commission members who formulated the Oregon Health plan,¹ I was particularly interested in the article by Dr Young.² I do have one small correction to his comment on page 75, "Services below this line were not to be available." This is commonly stated, but it would be more accurate to say, "Services below this line were not to be paid for." Oregonians desiring low-priority procedures that the state legislature has decided not to fund may still be able to receive them—and definitely will be able to receive a diagnosis—but the physicians and hospitals who provide these services will not be compensated for them. The hope is that this will cause Oregonians to think about where they want to spend their limited health care dollars and reward preventive and more efficacious treatment.

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Dr Young Responds

TO THE EDITOR: I am grateful to Dr Allen for clarifying this point. I meant to say that services below this line were not to be available through the State's Medicaid program. Dr Allen's hope that "this will encourage Oregonians to think about where they want to spend their limited health care dollars, and reward preventive and more efficacious treatment" is one that is shared by all of us concerned about meaningful rather than politically expedient health care reform.

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Physicians and Health Care Reform

TO THE EDITOR: The article on physicians' attitudes towards health care reform¹ was seriously flawed by what the authors describe as a "limitation"—the only choices they presented were managed competition, a single-payer system, or no change. Their justification, that these are the plans "that are currently receiving the most serious consideration nationally," simply will not do for two reasons: it is not true and what is being considered by non-physicians should have little bearing on deciding what physicians think is best.

It is not true because the Republican bill also has a great many supporters both in and out of Congress. It is true that it is not being considered for the next few months because the Democratic leadership in the Congress will not let it be considered there, but virtually all political observers I have heard or read lately agree that both options above will have no chance after the coming elections.

What is being considered by nonphysicians is barely relevant to what physicians think is best. For example, a patient has pneumonia, and we are offered the choice of treating him with tetracycline, aspirin, or fluconazole. Most of us would not fall for this; we would ask, "Where is the penicillin?" Similarly, we have a sick health care system caused by government interference in the physician-patient relationship and government-stimulated insurance interference in that relationship—including the antitrust stance of the government against physicians. The choices that Malter and colleagues offer us for treating the health care system are much more government and insurance company interference, nearly complete government interference in the relationship, or leave it as sick as it is. This is nonsense. We need a choice of how to get the government and insurance companies back where they belong—as advisors to patients and reimbursers of charges that they cover. The American Medical Association and Republican plans both have many aspects favorable to this goal, and a real survey should include them.

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REFERENCE

1. Malter AD, Emerson LL, Krieger JW: Attitudes of Washington State physicians toward health care reform. *West J Med* 1994; 161:29-33

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The Authors Respond

TO THE EDITOR: Dr Hamilton is correct to note that our survey did not assess the attitudes of physicians about all types of proposed health care reform. As we discussed in the article, we focused on managed competition and single-payer reforms for two reasons. At the time of the survey these were the proposals being considered most seriously nationally. Also, these were the only two plans—and indeed still are the only two plans—that would provide universal coverage.